

**This Page Is Inserted by IFW Operations
and is not a part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

(19)



Europäisches Patentamt

European Patent Office

Offi eur péen des br v ts



(11)

EP 0 656 198 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
07.11.2001 Bulletin 2001/45

(51) Int Cl.7: **A61F 2/06**

(21) Application number: **95102359.7**

(22) Date of filing: **14.02.1991**

(54) Device for collapsing a collapsible appliance for insertion into human organs and capable of resilient restoration

Einrichtung zum Zusammenklappen einer zusammenklappbaren und elastisch wieder in Form bringbaren, in ein menschliches Organ einsetzbaren Vorrichtung.

Dispositif pour plier un appareil pliable et capable de récupération élastique de forme pour insertion dans des organes humains

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB IT LI LU NL SE

(30) Priority: **15.02.1990 JP 3424790**

(43) Date of publication of application:
07.06.1995 Bulletin 1995/23

(62) Document number(s) of the earlier application(s) in
accordance with Art. 76 EPC:
91904456.0 / 0 472 731

(73) Proprietor: **Inoue, Kanji**
Kyoto-shi, Kyoto 606 (JP)

(72) Inventor: **Inoue, Kanji**
Kyoto-shi, Kyoto 606 (JP)

(74) Representative: **Tiedtke, Harro, Dipl.-Ing.**
Patentanwaltsbüro
Tiedtke-Bühling-Kinne & Partner
Bavariaring 4
80336 München (DE)

(56) References cited:
EP-A- 0 282 175 **US-A- 4 307 722**
US-A- 4 878 906

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 656 198 B1

Description

[0001] The present invention relates to a device for introducing a medium into a human body.

[0002] At present, treatment of, say, aortic aneurysms is conducted by implanting artificial blood vessels. In particular, the portion of a blood vessel which has an aneurysm is removed by resection, and an artificial blood vessel is implanted in place of the resected portion and connected to the remaining blood vessel by suturing.

[0003] The above mentioned method of surgically implanting artificial blood vessels for treatment of aortic aneurysms, however, is highly dangerous. Especially, emergency operation for treatment of a ruptured aneurysms has a low life-saving rate, and operation on dissecting aortic aneurysms is difficult and has a high death rate.

[0004] The document US-A-4878906 discloses a device for introducing a stent into a human body which comprises a tube having a side window adjacent to its front end. Furthermore, it comprises a second window in a certain distance from the first window. The tube is to be inserted through a stent. A wire which is inserted through the tube extends so as to protrude from the first window and to be reinserted into the second window, whereby the stent can be engaged and held by the tube and the wire.

[0005] The present invention has been accomplished to solve the above-mentioned problems encountered in the prior art. The object of the present invention is to provide a device for introducing a medium into a human body as well as a method for preparing a system containing such a device.

[0006] This object is achieved by the device according to claim 1 and by a method according to claim 11. Further advantageous features subject-matters of the dependent claims.

[0007] An advantage of the invention is that a medium or an appliance is provided which is collapsible for insertion into human organs, such as a blood vessel, and which can be brought to an affected or constricted part thereof, where the appliance is released so as to be expanded and implanted there without fail.

[0008] The appliance collapsible for insertion into human organs and capable of resilient restoration comprises a pair of foldable, elastic end wire rings are provided at opposite ends; that a plurality of foldable, elastic connecting wire rings having a generally circular shape when no external force is applied thereto are provided to bridge the opposite end wire rings and fixed thereto; and that a plurality of intermediate wire rings are provided between the opposite end wire rings so as to keep the connecting wire rings resiliently transformed to a generally elliptical shape.

[0009] A plurality of loops for pull strings to be passed through may be provided at a plurality of points which divide the circumference of each of the opposite end

wire rings.

[0010] The appliance for insertion into human organs comprises a pair of foldable, elastic end wire rings which are provided at the opposite ends of a tube made of cloth or a sheet of flexible material; a plurality of foldable, elastic connecting wire rings having a generally circular shape when no external force is applied thereto are provided to bridge the opposite end wire rings and fixed thereto; and a plurality of intermediate wire rings which are provided between the opposite end wire rings so as to keep the connecting wire rings resiliently transformed to a generally elliptical shape.

[0011] The appliance collapsible for insertion into human organs and capable of resilient restoration comprises a pair of foldable, elastic wire rings at the opposite ends of a tube made of cloth or a sheet of flexible material, and loops for a pull string to be passed through at a plurality of points which divide the circumference of each of the end wire rings.

[0012] The device for collapsing the appliance for insertion into human organs comprises a funnelled tube which is provided at its rear end with an inlet opening of a large diameter for the appliance to be inserted through from the front end thereof, and which has an intermediate tubular portion gradually reduced in diameter, and which terminates in a connecting tube having a smaller diameter than that of the appliance and adapted to be fitted into the rear end of a catheter.

[0013] When the appliance, which comprises a pair of foldable, elastic end wire rings provided at opposite ends; a plurality of foldable, elastic connecting wire rings having a generally circular shape when no external force is applied thereto and adapted to bridge the opposite end wire rings and fixed thereto; and a plurality of intermediate wire rings provided between the opposite end wire rings so as to keep the connecting wire rings resiliently transformed to a generally elliptical shape, is inserted into a human organ, the foldable, elastic end wire rings, the intermediate wire rings and the connecting wire rings are folded thereby to collapse the appliance, which is inserted into a catheter, and the appliance is released at an objective position in the human organ, whereupon the resilient restoring forces of the end wire rings, the intermediate wire rings and the connecting wire rings restore the appliance to its original tubular shape.

[0014] When the artificial body vessel comprising foldable, elastic end wire rings, intermediate wire rings and connecting wire rings is collapsed and inserted into a catheter, and released therefrom at an objective position (affected portion) in, say, a blood vessel, the resilient restoring forces of the end wire rings, the intermediate wire rings, the connecting wire rings cause the artificial body vessel to be restored to a tubular shape and pressed onto the inner wall of the blood vessel. Under the condition, the opposite end portions of the artificial body vessel are pressed onto the inner wall of the blood vessel, and the middle portion of the artificial body ves-

sel prevents the blood vessel from being closed by an external force after implantation, and the resilient restoring force of the connecting wire rings helps to keep the whole shape of the artificial body vessel when restored.

[0015] By inserting and releasing the artificial body vessel in a constricted part of a human organ, it is possible to expand the constricted part by the artificial body vessel.

[0016] The appliance has an advantage that it can be brought to a desired position such as an affected part of a blood vessel in collapsed condition without a surgical operation, and be released at the position so as to be resiliently restored to the original tubular shape thereby to implant the appliance or expand a constricted part of a human organ.

[0017] The appliance provided at those points which divide the circumference of the end wire rings with loops for pull strings to be passed through can be inserted into a catheter directly or through a collapsing device, and transmitted through the catheter by pulling the pull strings. The work of collapsing and inserting the artificial body vessel into a catheter can be done easily and quickly.

[0018] When the appliance is introduced into the opening of an enlarged diameter of the funnelled tube and moved therethrough to the connecting end of the pipe, the wire rings are smoothly folded into a predetermined shape, so that the whole appliance can be collapsed into a predetermined shape with ease and accuracy.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Fig. 1 is a perspective view of an artificial body vessel which does not form a part of the present invention.

[0020] Fig. 2 is a perspective view of a frame included in the artificial body vessel.

[0021] Fig. 3 is a perspective view of an example of the device according to the present invention for introducing a medium such as the above-mentioned artificial body vessel into a human body.

[0022] Fig. 4 is a perspective view showing the artificial body vessel through which the tube of the above-mentioned device is loosely inserted.

[0023] Fig. 5 is a perspective view showing the above-mentioned artificial body vessel and the tube of the above-mentioned device with a string to be passed through the loops on the artificial body vessel and wound about the wire within the tube.

[0024] Fig. 6 is a perspective view showing the above-string wound about the wire.

[0025] Fig. 7 shows a funnelled tube, A being a perspective view, B being a cross-sectional view along line X-X in A, and C being a cross-sectional view along line Y-Y in A.

[0026] Fig. 8 is a perspective view showing a front pull string and rear pull strings passed through the above-

mentioned front and rear loops.

[0027] Fig. 9 is a perspective view showing an artificial body vessel before being inserted into the above-mentioned funnelled tube.

5 [0028] Fig. 10 is a perspective view showing the artificial body vessel immediately before being inserted into the funnelled tube, with the tube of the above-mentioned device not shown.

10 [0029] Fig. 11 is a perspective view showing the artificial body vessel before insertion into the above-mentioned funnelled tube.

[0030] Fig. 12 is a cross-sectional view showing the tube of the above-mentioned device and the artificial body vessel in a catheter inserted into a blood vessel.

15 [0031] Fig. 13 is a cross-sectional view showing the catheter being pulled out leaving the tube of the above-mentioned device.

[0032] Fig. 14 shows the above-mentioned catheter being pulled, A being a cross-sectional view showing the catheter pulled out midway, and B being a cross-sectional view showing the catheter completely pulled out.

20 [0033] Fig. 15 is a cross-sectional view showing a balloon catheter moved into the artificial body vessel.

25 [0034] Fig. 16 is an enlarged perspective view showing the string released from the wire by withdrawing the wire relative to the tube of the above-mentioned device.

[0035] Fig. 17 shows the steps of folding the front end wire ring of the above-mentioned artificial body vessel.

30 [0036] Fig. 18 shows the steps of folding the rear end wire ring of the artificial body vessel.

[0037] Fig. 19 shows the steps of folding the front and rear end wire rings and the connecting wire rings of the artificial body vessel, A showing a condition before folding, and B showing a condition after folding.

35 [0038] Fig. 20 is a perspective view showing the above-mentioned artificial body vessel collapsed.

[0039] Fig. 21 is a perspective view of another example not part of the invention.

40 [0040] Figs. 22A and 22B show different examples not part of the invention in perspective view.

[0041] Fig. 23 is a perspective view of a further different example not part of the invention.

45 [0042] Fig. 24 is a perspective view of another embodiment of the device for introducing the artificial body vessel of the invention into a human body.

[0043] Fig. 25 is a perspective view of still another embodiment of the above device.

[0044] Fig. 26 is a perspective view of a different embodiment of the above device.

50 [0045] Fig. 27 is a view showing a different manner of collapsing the artificial body vessel.

[0046] Fig. 28 is a perspective view showing the above artificial body vessel in collapsed condition.

55 [0047] Fig. 29 is a perspective view showing a still different manner of collapsing the artificial body vessel.

[0048] Fig. 30 is a perspective view showing the artificial body vessel inserted into a constricted portion.

[0049] Fig. 31 is a perspective view showing the con-

stricted portion having been expanded by the above artificial body vessel.

[0050] Fig. 32 is a perspective view showing the constricted portion having been expanded by the above frame.

BEST MODES OF EMBODYING THE INVENTION

[0051] The invention will be described in detail with reference to the embodiments thereof shown in the accompanying drawings.

[0052] The appliance to be inserted into a human organ can take the form of, for example, an artificial blood vessel or an artificial body vessel or a frame for expanding constricted parts of human organs.

[0053] An artificial blood vessel 7 will be described below as an example of the appliance to be inserted into a human organ.

[0054] As shown in Fig. 1, the artificial blood vessel 7 is composed of a flexible tubular member made of cloth, film or the like, with a frame 32 for keeping the tubular shape. As shown in Fig. 2, the frame 32 has a three-dimensional construction comprising a pair of end wire rings 10 fixed to the opposite ends of the artificial blood vessel 7 by thread or adhesive, a plurality of connecting oblong wire rings 11 bridging the opposite end wire rings 10 and a plurality of intermediate wire rings 12 provided between the opposite end wire rings 10. The connecting wire rings 11 are made of wires of elastic material having a generally circular shape when no external force is applied thereto. As shown in Fig. 2, the connecting wire rings 11 are arranged between the opposite end wire rings 10 circumferentially thereof and fixed thereto. The elastic intermediate wire rings 12 are arranged between the opposite end wire rings 10. The intermediate wire rings 12 are partially fixed to the artificial blood vessel 7. Some of the intermediate wire rings 12 (in this embodiment, the two intermediate wire rings 12 adjacent the opposite end wire rings 10) are positioned outside the connecting wire rings 11 bridging the end wire rings 10 so as to transform their original circular shape into an elliptical shape as shown in Figs. 1 and 2 thereby to cause the connecting wire rings to store a resilient restoring force to return to their original circular shape. This resilient force acts as a spring force to restore the collapsed artificial blood vessel 7 to its original tubular shape. The original shape of the connecting wire rings 11 without any external force applied thereto is not limited to a strictly circular shape, but it may also be elliptical. In the latter case, the originally elliptical connecting wire rings 11 are previously deformed into a more elliptical shape by application of an external force thereto and then disposed between the opposite end wire rings 10. In the embodiment shown in Figs. 1 and 2, the middle one of the three intermediate rings 12 is positioned inside the oblong connecting wire rings 11 so as to prevent the connecting wire rings 11 from being pushed into the artificial blood vessel 7.

[0055] The connecting wire rings 11 and the intermediate wire rings 12 are not fixed to each other in order that the appliance may be smoothly collapsed without the connecting wire rings 11 and the intermediate wire rings 12 interfering with each other. It is possible to fix some of the intermediate wire rings 12 partially to the connecting wire rings 11. The connecting wire rings 11 may be interconnected to each other at one or more points thereof. That one of the intermediate wire rings 12 which is disposed outside the connecting wire rings 11 functions to transform the connecting wire rings 11 to a generally elliptical shape as mentioned above. On the other hand, the connecting wire rings 11 resiliently transformed to an elliptical shape continuously exerts on the intermediate rings 12 a force to expand thereby to help the intermediate wire rings 12 that have been folded to restore their original circular shape. In the illustrated embodiment, the connecting wire rings 11 are not directly fixed to the artificial blood vessel 7, but parts of them may be fixed to the artificial blood vessel 7, if necessary.

[0056] The above-mentioned end wire rings 10 are made of a flexible material which has a high resilient restoring force, such as Ti-Ni alloy. Of course the material is not limited to Ti-Ni alloy. The wires of the alloy are hard to weld, but the annular shape makes it easy to connect the members to each other by a string, so that it becomes easy to assemble the component members. The diameters of the end wire rings 10, the connecting wire rings 11 and the intermediate wire rings 12 are set to 20 mm to 39 mm in accordance with that of the artificial blood vessel 7. The length of the artificial blood vessel 7 is determined in accordance with the length of the portion of an organ at which the artificial blood vessel is to be implanted.

[0057] A pair of loops 13 made of thread at two opposite positions of the circumference of the opening at one of the opposite ends of the artificial blood vessel 7 to which the end wire rings 10 are fixed. If necessary, similar loops 13a made of thread may also be provided at two opposite positions of the circumference of the opening at the opposite end of the artificial blood vessel 7. In this case, the position of the loops 13a are circumferentially displaced 90° from the loops 13.

[0058] The artificial blood vessel 7 of the above-mentioned construction is introduced into a human body vessel by means of a device as shown in Fig. 3 for introducing a medium into a human body vessel. The device comprises a flexible metallic tube 2 formed with a side window 1 adjacent the front end thereof, a string 4 having one end fixed to the tube 2 adjacent the side window 1, and a wire 3 slidably inserted into the tube 2.

[0059] By using the device of the above-mentioned construction for introducing a medium into a human body vessel, the artificial blood vessel 7 of the invention is introduced into a target position (an affected part 26) of a blood vessel 9 which is part of a human body in the following manner.

[0060] The tube 2 is inserted through the artificial blood vessel 7 of the above-mentioned construction as shown in Fig. 4, and a string 4 is passed through the loops 13 provided at the front end of the artificial blood vessel 7 and wound about the wire 3 in a half, one or several turns at the side window 1 of the tube 2 as shown in Fig. 5 thereby to hold the artificial blood vessel 7 on the wire 3 inserted into the tube 2. In particular, by taking the front end portion of the wire 3 out of the side window 1, winding the string 4 about the wire 3, and then inserting the front end of the wire 3 into the tube 2, it is possible to easily wind the string 4 about the wire 3 at the side window 1. If the string 4 is formed with an enlarged portion such as a knot 14 as shown in Fig. 6, the string 4 is nipped between the edge of the side window 1 and the wire 3, so that the string 4 is held the more securely. A plurality of strings 4 may be provided as shown in Fig. 24.

[0061] With the artificial blood vessel 7 held on the tube 2 by the wire 3 in the above-mentioned manner, the tube 2 is inserted into a catheter 8 as far as the target position (the affected part) 26 in the blood vessel 9. To this end, the tube 2 may be pushed directly into the catheter 8 through its rear end, and the artificial blood vessel 7 may be pulled by the string 4 thereby to collapse and introduce the vessel 7 into the catheter 8 while deforming and folding the wire ring 10 at the front end of the vessel 7. Alternatively, the artificial blood vessel 7 may be collapsed beforehand by using a collapsing device as shown in Fig. 7, so that the collapsed blood vessel is inserted into the catheter 8.

[0062] A method of collapsing the artificial blood vessel 7 beforehand by the collapsing device shown in Fig. 7 and inserting it into a catheter will now be described below.

[0063] In Fig. 7, the reference numeral 18 designates a funnelled tube, the rear end portion of which is provided with an inlet opening 18a of an enlarged diameter, through which the tubular artificial blood vessel 7 is inserted into the tube 18 from the front end thereof. The tube 18 has a middle portion gradually reduced in diameter and a front end portion made of a metallic tube circular in cross section and smaller in diameter than the artificial blood vessel 7 and formed into a connector 19 capable of being fitted into the rear end of the catheter 8 detachably therefrom. In Fig. 7, the reference numeral 15 designates a check valve provided in the rear end portion of the catheter 8 and made of elastic membrane, in which a normally closed hole 17 is formed. When the connector 19 composed of a metallic tube is inserted into the rear end portion of the catheter 8, the connector 19 pushes open the closed hole 17 in the elastic membrane so as to be inserted therethrough.

[0064] In the illustrated embodiment, the funnelled tube 18 has an elliptical cross-sectional shape, with the loops 13 being provided at two points bisecting the circumference of the front end wire ring 10. If loops 13 are provided at three points trisecting the circumference of

the wire ring 10, the funnel of the tube 18 is made triangular in cross section. If loops 13 are provided at four points quadrisectioning the circumference of the wire ring 10, the funnel of the tube 18 is made square in cross section. In the embodiment shown in Fig. 8, a front pull string 20 is passed through the loops 13 provided at two opposite positions on the circumferential edge of the opening at the front end of the artificial blood vessel 7, and rear pull strings 21 are passed through the loops 13a provided at two opposite positions on the circumferential edge of the opening at the other end of the artificial blood vessel 7, with a rod-like grip 22 being fixed to the ends of the rear pull strings 21.

[0065] Under this condition, a balloon catheter 23 is loosely fitted over the tube 2 of the introducing device so that the front end of the balloon catheter 23 is positioned about 2 to 3 cm apart from the rear end of the artificial blood vessel 7 as shown in Fig. 11. Then a fixing member 24 on the balloon catheter 23 is fastened to fix the catheter 23 to the tube 2 so that the catheter 23 can be moved together with the tube 2.

[0066] With the funnelled tube 18 disconnected from the catheter 8, the front pull string 20 is inserted through the rear end of the funnelled tube 18 and pulled forwardly from the front end of the connector tube 19, and at the same time the front end portion of the tube 2 is inserted a certain length into the funnelled tube 18 as shown in Figs. 9 and 10. Under this condition, with a rearward pulling force applied to the rear end wire ring 10 of the artificial blood vessel 7 by the grip 22, the artificial blood vessel 7 is introduced into the funnelled tube 18 through the enlarged inlet opening 18a thereof by pulling forwardly the front pull string 20. Let it be assumed here for convenience of explanation that the circumference of the front end wire ring 10 is quadrisectioned by four imaginary points which (or the positions adjacent to which) will be referred to as the first, second, third and fourth points 41₁, 42₁, 43₁ and 44₁ respectively; that similarly the circumference of the rear end wire ring 10 is quadrisectioned by the first, second, third and fourth points 41₂, 42₂, 43₂ and 44₂ respectively; and that the loops 13 on the front end wire ring 10 are positioned at the first and third points 41₁ and 43₁ while the loops 13a on the rear end wire ring 10 are positioned at the second and fourth points 42₂ and 44₂. The artificial blood vessel 7 is so arranged with respect to the funnelled tube 18 that the line connecting the first and third points 41₁ and 43₁ on the front end wire ring 10 lies substantially along the short axis of the ellipse of the enlarged inlet opening 18a as shown in Fig. 7B while the line connecting the second and fourth points 42₁ and 44₁ lies along the long axis of the ellipse. In short, the artificial blood vessel 7 is set with respect to the funnelled tube 18 as shown in Fig. 10.

[0067] Under this condition, as the front pull string 20 is pulled, the first and third points 41₁ and 43₁, which are the two opposite points on the front end wire ring 10 of the artificial blood vessel 7 where the loops 13 are provided, are pulled by the front pull string 20, so that

the front end wire ring 10 is collapsed flatly with the first and third points 41₁ and 43₁ where the loops 13 are provided approaching each other. Since the first and third points 41₁ and 43₁ are pulled ahead, the collapsed front end wire ring 10 is inserted into the funnelled tube 18 while being further collapsed, with the opposite second and fourth points 42₁ and 44₁ on the collapsed front end wire ring 10 being positioned rearwardly and approaching each other. In short, the front end wire ring 10 is transformed from the condition shown in Fig. 17A to the condition shown in Fig. 17B and thence to the condition shown in Fig. 17C, with the first and third points 41₁ and 43₁ forming forwardly directed peaks and the second and fourth points 42₁ and 44₁ forming the bottoms of forwardly directed valleys, so that the front end wire ring 10 as a whole takes a wavy shape.

[0068] As the front pull string 20 is pulled further forwardly, with the rear pull strings 21 holding the rear end wire ring 10 at the opposite loops 13a (provided at the second and fourth points 42₂ and 44₂ of the rear end wire ring 10), the rear end wire ring 10 is pulled rearwardly at the loops 13a. At the same time, since the front end of the artificial blood vessel 7 is pulled forwardly by the above-mentioned front pull string 20, the rear end wire ring 10 is collapsed flatly and inserted into the funnelled tube 18, with the first and third points 41₂ and 43₂ advancing ahead while approaching each other, and the second and fourth points 42₂ and 44₂ being positioned rearwardly and approaching each other. In short, the rear end wire ring 10 is transformed from the condition shown in Fig. 18A to the condition shown in Fig. 18B and thence to the condition shown in Fig. 18C, with the second and fourth points 42₂ and 44₂ forming rearwardly directed peaks, and the first and third points 41₂ and 43₂ forming the bottoms of rearwardly directed valleys, so that the rear end wire ring 10 as a whole takes a wavy shape.

[0069] Figs. 19A and 19B show the relation between the front and rear end wire rings 10 and the connecting wire rings 11 of the artificial blood vessel 7 at different steps of collapsing the vessel 7 in the above-mentioned manner. (For simplicity of illustration, the intermediate rings 12 are not shown in the figures.) In short, the rings 10 and 11 are folded as shown in Figs. 19A and 19B. Under the folded condition shown in Fig. 19B, the connecting wire rings 11 extend almost linearly and will not be loosened. Fig. 20 shows the artificial blood vessel 7 collapsed in the above-mentioned manner. After the artificial blood vessel 7 has been introduced through the enlarged inlet 18a of the funnelled tube 18 into the connecting tube 19 while being collapsed in the above-mentioned manner, the front and rear pull strings 20 and 21 are untied and pulled at their ends so as to be withdrawn from the loops 13 and 13a.

[0070] On the other hand, the catheter 8 was previously inserted through, say, the coxal artery adjacent the groin into an aorta 9 as far as the front end of the catheter was positioned a little beyond the affected part such as

an aneurysm 26 of the aorta. Then the metallic connecting end 19 of the funnelled tube 18 is inserted through the hole 17, that is, the check valve 16 in the elastic membrane at the rear end of the catheter 8, and the tube 2 of the introducing device containing the wire 3 is inserted into the catheter 8 as far as the front end of the tube 2 containing the wire 3 is positioned adjacent the front end of the catheter 8 as shown in Fig. 12 thereby to place the artificial blood vessel 7 held by the wire 3 at the objective position in the catheter 8. Then, as the catheter 8 is withdrawn as shown in Figs. 13 and 14, with the tube 2 holding the collapsed artificial blood vessel 7 by the wire 3 left at the objective position, the collapsed artificial blood vessel 7 in the catheter 8 is released into the blood vessel 9 while expanding gradually from the front end as shown in Figs. 13, 14A and 14B. The released artificial blood vessel 7 is restored to its original tubular contour by the resiliency of the end wire rings 10 and the connecting wire rings 10 and urged against the inner wall of the blood vessel 9. If the released artificial blood vessel 7 is displaced from the proper position, the tube 2 is moved forwardly or rearwardly to adjust the position of the artificial blood vessel 7.

[0071] Then the fixing member 24 is loosened to disconnect the balloon catheter 23 from the tube 2, and the balloon catheter 23 is advanced along the tube 2 into the artificial blood vessel 7 as far as the front end of the balloon catheter 23 reaches the front end of the artificial blood vessel 7 as shown in Fig. 15, whereupon the balloon is inflated as shown by dash-and-dot lines in Fig. 15 thereby to expand the artificial blood vessel 7 completely and securely fix it onto the inner wall of the blood vessel 9.

[0072] After the artificial blood vessel 7 has been fixed, the balloon is deflated and the balloon catheter 23 is pulled out. Then it is confirmed that the artificial blood vessel 7 has been fixed onto the inner wall of the blood vessel 9, and the wire 3 is pulled out of the tube 2. As the front end of the wire 3 passes the rear edge of the side window 1 of the tube 2 as shown in Fig. 16, the string 4 that has been caught by the wire 3 at the window 1 is released from the wire 3. Under this condition, as the tube 2 is pulled out, the string 4 slips out of the loops 13 of the artificial blood vessel 7, and the tube 2 comes out leaving the artificial blood vessel 7 in place in the blood vessel 9.

[0073] In the above embodiment, the balloon catheter 23 is used. It is possible to make the artificial blood vessel 7 contact the inner wall of the blood vessel 9 by the resiliency of the artificial blood vessel 7 alone without using a balloon catheter.

[0074] Another example of the artificial blood vessel 7 of the invention will be described with reference to Fig. 21. In this embodiment, the opposite end portions of the connecting wire rings 11 project outwardly along the axis of the artificial blood vessel 7 beyond the front and rear end wire rings 10 thereof. In this arrangement, each of

th connecting wire rings 11 is fixed to each of the front and rear end wire rings 10 at two points 30 and 31, so that when the wire rings 10 once folded are restored to their original shape, the resiliency of the connecting wire rings 11 to return to their circular shape acts on the end wire rings 10 to help them to return to their original circular shape. The projection of the connecting wire rings 11 beyond the opposite ends of the artificial blood vessel 7 prevents the bordering portions of the blood vessel 9 and the implanted artificial blood vessel 7 from becoming stepped thereby to help the inner wall of the artificial blood vessel 7 to join the inner wall of the blood vessel 9 smoothly and evenly.

[0075] As shown in Figs. 22A and 22B, the connecting wire rings 11 may be fixed to the end wire rings 10 at the crossing points of each adjacent two of the connecting wire rings 11.

[0076] As shown in Fig. 22B, an additional pair of wire rings 10a may be fixed to the axially outwardly projecting ends of the connecting wire rings 11 beyond the opposite end wire rings 10. The added rings 10a not only prevent the projecting ends of the connecting wire rings 11 from scratching the inner wall surface of the blood vessel 9, but also help the opposite ends of the connecting wire rings 11 to expand into close contact with the inner wall surface of the blood vessel 9 thereby to prevent the implanted artificial vessel 7 from being carried away downstream by blood flow.

[0077] As shown in Fig. 23, projections 35 may be formed on the exterior wall surface of the artificial blood vessel 7. The projections 35 may be more or less V-shaped as shown in Fig. 23 or wart-like, or have a pointed end, or take various other forms. The projections may be made of wire, hard thread, rubber or any other suitable materials. The projections 35 may be formed on the end wire rings 10 or the connecting wire rings 11, or on the outer surface of the cloth or film constituting the body of the artificial blood vessel 7. The projections 35 may stand perpendicular to the exterior surface of the artificial blood vessel 7, or inclined rearwardly. The projections 35 provided on the exterior surface of the artificial blood vessel 7 are pushed into the inner wall of the blood vessel 9 and provide frictional resistance to prevent the artificial blood vessel 7 from being carried away downstream by blood flow.

[0078] In the above-mentioned embodiments, the end wire rings 10, the connecting wire rings 11 and the intermediate wire rings 12 are arranged outside the cloth tube of the artificial blood vessel 7. They may be arranged inside the cloth tube.

[0079] Fig. 25 shows another example of the device for introducing a medium such as the artificial blood vessel 7 into a human body. In this example, the tube 2 is provided at the front end thereof with a soft, flexible guide tube 5 comprising a coil made of soft metal or synthetic resin such as polyethylene, or a tube made of soft synthetic resin or rubber. The soft, flexible tube 5 is provided on the front end of the tube 2 is intended to prevent

the tube 2 from injuring the inner wall of the blood vessel 9.

[0080] Fig. 26 shows a third example of the device for introducing a medium into a human body. In this example, a short tube 2 is provided at its front end with a short guide tube 5 and at its rear end with a long guide tube 6. The short and long guide tubes 5 and 6 comprise a coil made of soft metal or synthetic resin such as polyethylene, or a tube made of soft synthetic resin or rubber. With the short and long flexible guide tubes 5 and 6 provided at the front and rear ends, respectively, of the tube 2, when the tube 2 is inserted into a meandrous blood vessel, the flexible front and rear guide tubes can move smoothly and easily along the meandrous blood vessel without danger of injuring the inner wall of the blood vessel 9.

[0081] In the above-mentioned embodiments, when the artificial blood vessel 7 is collapsed and inserted into the catheter 8, the front end wire ring 10 is folded at the first, second, third and fourth points 41₁, 42₁, 43₁ and 44₁ on the circumference of the ring, and the rear end wire ring 10 is folded at the first, second, third and fourth points 41₂, 42₂, 43₂ and 44₂.

[0082] In Figs. 27 and 28, the front and rear end wire rings 10 have their respective circumferences divided into eight equal arcs by the first, second, third, fourth, fifth, sixth, seventh and eighth imaginary points 51₁, 52₁, 53₁, 54₁, 55₁, 56₁, 57₁ and 58₁, and 51₂, 52₂, 53₂, 54₂, 55₂, 56₂, 57₂ and 58₂, respectively. Loops 13 are provided on the front end wire ring 10 at the first, third, fifth and seventh points 51₁, 53₁, 55₁ and 57₁ while loops 13a are provided on the rear end wire rings 10a at the second, fourth, sixth and eighth points 52₂, 54₂, 56₂ and 58₂.

[0083] With the artificial blood vessel 7 having been set relative to a funnelled tube 18 provided with an enlarged inlet opening 18a square in cross section in such a manner that the first, third, fifth and seventh points 51₁, 53₁, 55₁ and 57₁ of the front end wire ring 10 are positioned about the middle of the four sides of the inlet opening 18a as shown in Fig. 27, as the front pull strings 20 are pulled, the first, third, fifth and seventh points 51₁, 53₁, 55₁ and 57₁ of the front end wire ring 10 where the loops 13 are provided are pulled by the strings 20 forwardly, so that the front end wire ring 10 is collapsed with the first, third, fifth and seventh points 51₁, 53₁, 55₁ and 57₁ advancing axially ahead while approaching each other. As the first, third, fifth and seventh points 51₁, 53₁, 55₁ and 57₁ are pulled ahead forwardly through the funnelled tube 18, the folded front end wire ring 10 is inserted into the tube 18, with the second, fourth, sixth and eighth points 52₁, 54₁, 56₁ and 58₁ on the front end wire ring 10 being positioned rearwardly and approaching each other. In other words, the front end wire ring 10 as a whole takes a wavy form, with the first, third, fifth and seventh points 51₁, 53₁, 55₁ and 57₁ on the front end wire ring 10 where the loops 13 are provided being positioned at forwardly directed peaks and

the second, fourth, sixth and eighth points 52₁, 54₁, 56₁ and 58₁ being positioned at the bottoms of forwardly directed valleys.

[0084] Under the condition, as the front pull strings 20 are pulled further forwardly, with the rear end wire ring 10 being held by the rear pull strings 21 at the second, fourth, sixth and eighth points 52₁, 54₁, 56₁ and 58₁, where the loops 13a are provided, the rear end wire ring 10 is inserted into the funnelled tube 18 while being folded and deformed, with its first, third, fifth and seventh points 51₂, 53₂, 55₂ and 57₂ being pulled ahead into the funnelled tube 18 and approaching each other, and the second, fourth, sixth and eighth points 52₂, 54₂, 56₂ and 58₂ being positioned rearwardly and approaching each other. In other words, the rear end wire ring 10 as a whole takes a wavy form, with the second, fourth, sixth and eighth points 52₂, 54₂, 56₂ and 58₂ of the rear end wire ring where the loops 13a are provided being positioned at rearwardly directed peaks, and the first, third, fifth and seventh points 51₂, 53₂, 55₂ and 57₂ thereof being positioned at the bottoms of rearwardly directed valleys as shown in Fig. 28.

[0085] In Fig. 29, the front and rear end wire rings 10 have their circumferences divided into six equal arcs by six imaginary points, which (or the positions adjacent to which) will be referred to as the first, second, third, fourth, fifth and sixth points 61₁, 62₁, 63₁, 64₁, 65₁ and 66₁, and 61₂, 62₂, 63₂, 64₂, 65₂ and 66₂, respectively. Loops 13 are provided on the front end wire ring 10 at the first, third and fifth points 61₁, 63₁ and 65₁, while loops 13a are provided on the rear end wire ring 10 at the second, fourth and sixth points 62₂, 64₂ and 66₂.

[0086] With the artificial blood vessel 7 having been set relative to the funnelled tube 18 provided with an enlarged inlet opening 18a triangular in cross section in such a manner that the first, third and fifth points 61₁, 63₁ and 65₁ of the front end wire ring 10 are positioned about the middle of the sides of the inlet 18a as shown in Fig. 29, as the front pull strings 20 are pulled, the first, third and fifth points 61₁, 63₁ and 65₁ of the front end wire rings 10 where the loops 13 are provided are pulled by the front pull strings 20 forwardly so that the front end wire ring 10 is collapsed, with the first, third and fifth points 61₁, 63₁ and 65₁ advancing axially ahead while approaching each other. As the first, third and fifth points 61₁, 63₁ and 65₁ are pulled ahead forwardly through the funnelled tube 18, the folded front end wire ring 10 is inserted into the tube 18, with the second, fourth and sixth points 62₁, 64₁ and 66₁ being positioned rearwardly and approaching each other. In other words, the front end wire ring 10 as a whole takes a wavy form, with the first, third and fifth points 61₁, 63₁ and 65₁ being positioned at forwardly directed peaks and the second, fourth and sixth points 62₁, 64₁ and 66₁ being positioned at the bottoms of forwardly directed valleys.

[0087] Under this condition, as the front pull strings 20 are pulled further forwardly, with the rear end wire ring 10 being held by the rear pull strings 20 at the sec-

ond, fourth and sixth points 62₂, 64₂ and 66₂ thereof where the loops 13a are provided, the rear end wire ring 10 is inserted into the funnelled tube 18 while being folded and deformed, with the first, third and fifth points 61₁, 63₂ and 65₂ being pulled ahead forwardly into the tube 18, and the second, fourth and sixth points 62₂, 64₂ and 66₂ being positioned rearwardly and approaching each other. In other words, the rear end wire ring 10 as a whole takes a wavy form, with the second, fourth and sixth points 62₂, 64₂ and 66₂ where the loops 13a are provided being positioned at rearwardly directed peaks, and the first, third and fifth points 61₂, 63₂ and 65₂ being positioned at the bottoms of rearwardly directed valleys.

[0088] In the above-mentioned embodiments, the front and rear end wire rings 10 have their circumferences divided into four, six and eight equal arcs. They may be divided by ten or any other even number of points, at each of which a loop 13, 13a may be provided in those cases, the loops 13, 13a are most preferably provided at those positions on the wire rings which correspond to the ends of the connecting wire ring 11, or at the middle positions on the end wire rings between the ends of each adjacent two of the connecting wire rings 11. With the loops 13 and 13a provided at such positions, it is possible to transform the wire rings 10 to a uniform wavy form. In the above embodiments, the connecting wire rings 11 are circular when no external force is applied to them. They may be elliptical when no external force is applied to them.

[0089] In the above embodiments, the appliance to be inserted into a human organ is used as, by way of example, an artificial blood vessel. It may be used as an artificial body vessel for expanding constricted parts of human organs. In particular, the artificial body vessel 7 is inserted into a constricted part 26a of a human organ 9a as shown in Fig. 30 in the same manner as previously mentioned with respect to the artificial blood vessel, and then released at the position shown in Fig. 30, whereupon the constricted part 26a of the human organ 9a is expanded by the resiliency of the artificial body vessel of the same construction as the previously mentioned artificial blood vessel 7 as shown in Fig. 31.

[0090] For expanding constricted parts of human organs not only the artificial body vessel 7 shown in Figs. 30 and 31 but also those shown in Fig. 21, 22A, 22B and 23 or those which have the same construction of any of the other embodiments of the invention may be used.

[0091] Fig. 32 shows an example of the appliance for expanding a constricted part 26a of a human organ 9a, which comprises only a frame 32 without the tubular cloth or sheet used in the previously mentioned artificial blood vessel. In this case, only the frame 32 is inserted into the constricted part 26a of the human organ 9a in the same manner as previously mentioned, and then released in the constricted part 26a as shown in Fig. 32 to expand the part by the resilient restoring force of the frame 32. Not only the frame 32 of the construction

shown in Fig. 32 but also those frames 32 of the artificial blood vessels 7 shown in Figs. 21, 22A, 22B and 23 without the tubular cloth or sheet may be used as occasions demand.

POSSIBLE APPLICATIONS IN INDUSTRY

[0092] As mentioned above, the appliance collapsible for insertion into human organs and capable of resilient restoration is useful as an artificial blood vessel or in expanding constricted parts in human organs. The device of the invention is useful in collapsing the appliance, inserting the collapsed appliance into a catheter and releasing the appliance therefrom at a required position in the human body.

Claims

1. A device for introducing a medium into a human body comprising:

a tube (2) having a front end, wherein said tube is formed with a side window (1) adjacent its front end, said tube (2) is prepared to be inserted through said medium;

a wire (3) inserted through said tube, slidably received therein and extended through said front end of said tube so as to extend inside and along said side window (1) of said tube; and at least one string (4), having a first end being fixed to said tube adjacent said side window (1) and a second end, said string (4) being arranged so as to be engaged with said medium and wound around said wire (3) where said wire extends inside and along said side window of said tube, so as to have its second end releasably fixed to said tube (2).

2. A device according to claim 1, further comprising a flexible guide tube connected to said front end of said tube.

3. A device according to claim 2, wherein said flexible guide tube further comprises a coil spring.

4. A device according to claim 2 or 3, wherein said flexible guide tube is short.

5. A device according to claim 1, further comprising a long flexible guide tube connected to a rear end of said tube.

6. A device according to claim 5, wherein said long flexible guide tube further comprises a coil spring.

7. A device according to any of the preceding claims, wherein said wire (3) is slidably supported within

said tube (2).

8. A device according to claim 1, wherein said at least one string (4) further comprises a second end, said second end being nipped between said tube (2) and said wire (3) so as to be held by said tube and said wire.

9. A device according to claim 8, wherein said second end of said at least one string (4) is formed into a knot (14).

10. A system consisting of a device according to any of the preceding claims and a medium to be introduced into a human body, wherein a front opening of said medium is provided with at least one loop (13) through which said string (4) is passed.

11. Method for preparing a system according to claim 10 to be subsequently inserted into a catheter comprising the following steps:

- introducing said tube (2) through said medium so that it extends beyond its front end;
- passing said string (4) through said loops (13) and winding it about said wire (3) in a half, one or several turns at the side window (1) of said tube (2).

12. Method according to claim 11, further comprising the steps of

- taking said front end portion of said wire (3) out of the side window (1);
- winding said string (4) about said wire (3);
- inserting the front end of said wire (3) into said tube (2).

13. Method according to claim 11, further comprising the step of

- nipping said string (4) between the edge of the side window (1) and said wire (3) so that the string (4) is held securely.

Patentansprüche

1. Vorrichtung zum Einführen eines Mediums in einen menschlichen Körper mit:

einem Rohr (2), das ein vorderes Ende hat, wobei das Rohr mit einem Seitenfenster (1) ausgebildet ist, das zu dem vorderen Ende des Rohres benachbart ist, und wobei das Rohr (2) vorbereitet worden ist, durch das Medium eingesetzt zu werden;

einem durch das Rohr eingesetzten Draht (3),

- der darin gleitfähig aufgenommen ist und sich durch das vordere Ende des Rohres so erstreckt, daß es sich innerhalb und entlang des Seitenfensters (1) des Rohres erstreckt; und zumindest einem Faden (4), der in erstes Ende hat, das an dem Rohr benachbart zu dem Seitenfenster (1) befestigt ist, und der ein zweites Ende hat, wobei der Faden (4) so angeordnet ist, daß er mit dem Medium im Eingriff ist und dort um den Draht (3) herum gewunden ist, wo sich der Draht innerhalb und entlang des Seitenfensters des Rohres erstreckt, wobei sein zweites Ende lösbar an dem Rohr (2) befestigt ist.
2. Vorrichtung nach Anspruch 1, die ferner ein flexibles Führungsrohr aufweist, das mit dem vorderen Ende des Rohrs verbunden ist.
 3. Vorrichtung nach Anspruch 2, wobei das flexible Führungsrohr ferner eine Schraubenfeder aufweist.
 4. Vorrichtung nach den Ansprüchen 2 oder 3, wobei das flexible Führungsrohr kurz ist.
 5. Vorrichtung nach Anspruch 1, die ferner ein langes flexibles Führungsrohr aufweist, das mit dem hinteren Ende des Rohres verbunden ist.
 6. Vorrichtung nach Anspruch 5, wobei das lange flexible Führungsrohr ferner eine Schraubenfeder aufweist.
 7. Vorrichtung nach mindestens einem der vorstehenden Ansprüche, wobei der Draht (3) innerhalb des Rohres (2) gleitfähig gestützt ist.
 8. Vorrichtung nach Anspruch 1, wobei der zumindest eine Faden (4) ferner ein zweites Ende aufweist, wobei das zweite Ende zwischen dem Rohr (2) und dem Draht (3) eingeklemmt ist, so daß es durch das Rohr und den Draht gehalten ist.
 9. Vorrichtung nach Anspruch 8, wobei das zweite Ende des zumindest einen Fadens (4) als Knoten (14) ausgebildet ist.
 10. System, das aus einer Vorrichtung nach mindestens einem der vorstehenden Ansprüche und einem Medium zum Einführen in einen menschlichen Körper besteht, wobei eine vordere Öffnung des Mediums mit zumindest einer Schlinge (13) versehen ist, durch die der Faden (4) hindurchgeführt wird.
 11. Verfahren zum Vorbereiten eines Systems nach Anspruch 10, das später in ein Katheter eingesetzt wird, und das die folgenden Schritte aufweist:
 - Einführen des Rohres (2) durch das Medium derart, daß es sich über sein vorderes Ende hinaus erstreckt;
 - Hindurchführen des Fadens (4) durch die Schlinge (13), wobei er an dem Seitenfenster (1) des Rohres (2) mit einer halben Wicklung, einer ganzen Wicklung oder mehreren Wicklungen um den Draht (3) herumgewunden wird.
 12. Verfahren nach Anspruch 11, das ferner die Schritte aufweist:
 - Entnehmen des vorderen Endabschnittes des Drahtes (3) aus dem Seitenfenster (1);
 - Wickeln des Fadens (4) um den Draht (3);
 - Einsetzen des vorderen Endes des Drahtes (3) in das Rohr (2).
 13. Verfahren nach Anspruch 11, das ferner den Schritt aufweist:
 - Einklemmen des Fadens (4) zwischen der Kante des Seitenfensters (1) und dem Draht (3), so daß der Faden (4) sicher gehalten wird.

Revendications

1. Dispositif pour introduire un support dans un corps humain comprenant :

un tube (2) ayant une extrémité frontale, ledit tube ayant une fenêtre latérale (1) adjacente à son extrémité frontale, ledit tube (2) est préparé pour être inséré dans ledit support ;

un fil (3) inséré dans ledit tube par glissement et étendu à travers ladite extrémité frontale dudit tube de telle sorte qu'il s'étende à l'intérieur et le long de ladite fenêtre latérale (1) dudit tube et

au moins un cordon (4) ayant une première extrémité fixée audit tube à proximité de ladite fenêtre latérale (1) et une seconde extrémité, ledit cordon (4) étant arrangé de telle sorte qu'il soit engagé dans ledit support et

entouré autour dudit fil (3) où ledit fil s'étend à l'intérieur et le long de ladite fenêtre latérale dudit tube, de telle sorte que sa seconde extrémité soit fixée de manière réversible audit tube (2).

2. Dispositif selon la revendication 1 comprenant en outre un tube de guidage flexible connecté à ladite extrémité frontale dudit tube.

3. Dispositif selon la revendication 2 dans lequel ledit

tube de guidage flexible comprend en outre un ressort enroulé.

4. Dispositif selon la revendication 2 ou 3 dans lequel ledit tube de guidage flexible est court. 5
5. Dispositif selon la revendication 1 comprenant en outre un long tube de guidage flexible connecté à une extrémité arrière dudit tube. 10
6. Dispositif selon la revendication 5 dans lequel ledit long tube de guidage flexible comprend en outre un ressort enroulé.
7. Dispositif selon l'une quelconque des revendications précédentes dans lequel ledit fil (3) est supporté par glissement dans ledit tube (2). 15
8. Dispositif selon la revendication 1 dans lequel ledit au moins un cordon (4) comprend en outre une seconde extrémité; ladite seconde extrémité étant pincée entre ledit tube (2) et ledit fil (2) de telle sorte qu'il soit maintenu par ledit tube et ledit fil. 20
9. Dispositif selon la revendication 8, dans lequel ladite seconde extrémité dudit au moins un cordon (4) est nouée pour former un noeud (14). 25
10. Un système consistant en un dispositif selon l'une quelconque des revendications précédentes et en un support à introduire dans un corps humain, dans lequel une ouverture frontale dudit support est équipée d'au moins une boucle (13) à travers laquelle ledit cordon (4) est passé. 30
11. Méthode de préparation d'un système selon la revendication 10 pour être ensuite inséré dans un cathéter comprenant les étapes suivantes : 35
 - introduction dudit tube (2) à travers ledit support de telle sorte qu'il s'étende au-delà de son extrémité frontale, 40
 - passage dudit cordon (4) à travers lesdites boucles (13) et enroulement autour dudit fil (3) en un demi, un ou plusieurs tours au niveau de la fenêtre latérale (1) dudit tube (2). 45
12. Méthode selon la revendication 11 comprenant en outre les étapes suivantes 50
 - passage de ladite portion frontale dudit fil (3) hors de la fenêtre latérale (1),
 - enroulement dudit cordon (4) autour dudit fil (3), 55
 - insertion de l'extrémité frontale dudit fil (3) dans

ledit tube (2).

13. Méthode selon la revendication 11 comprenant en outre l'étape suivante :

- pincement dudit cordon (4) entre le bord de la fenêtre latérale (1) et ledit fil (3) de telle sorte que le cordon (4) soit fixé de manière sûre.

FIG.1

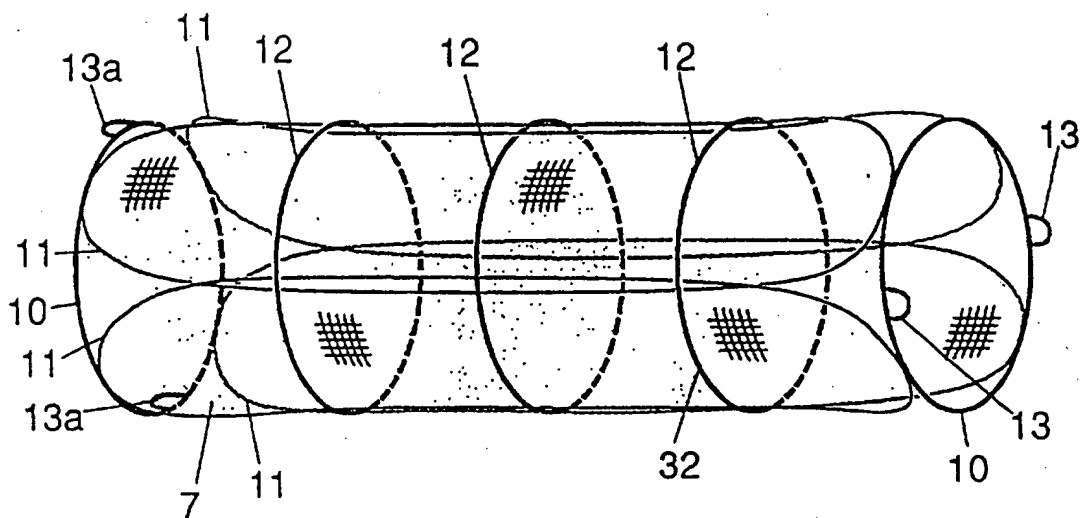
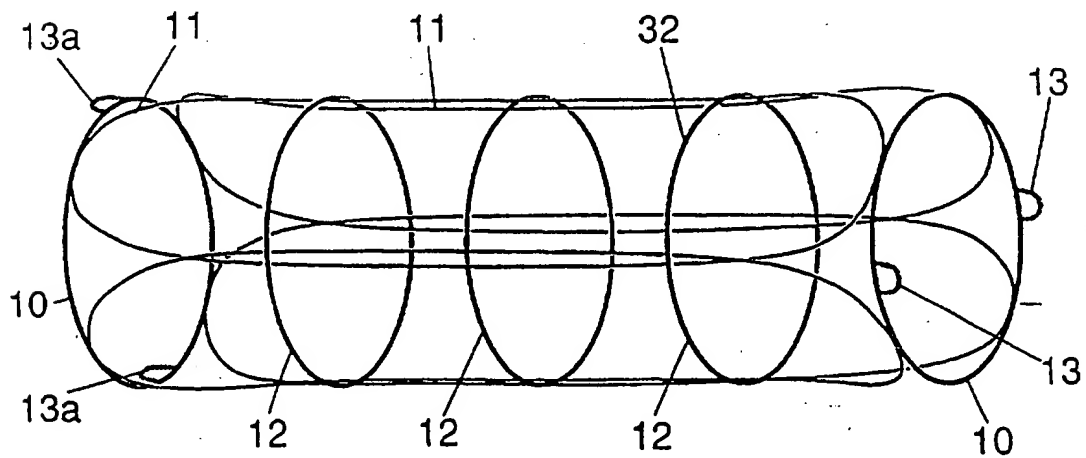


FIG.2



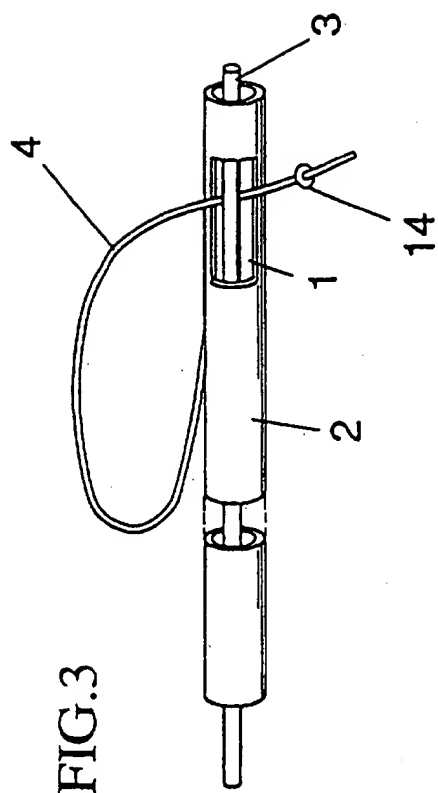
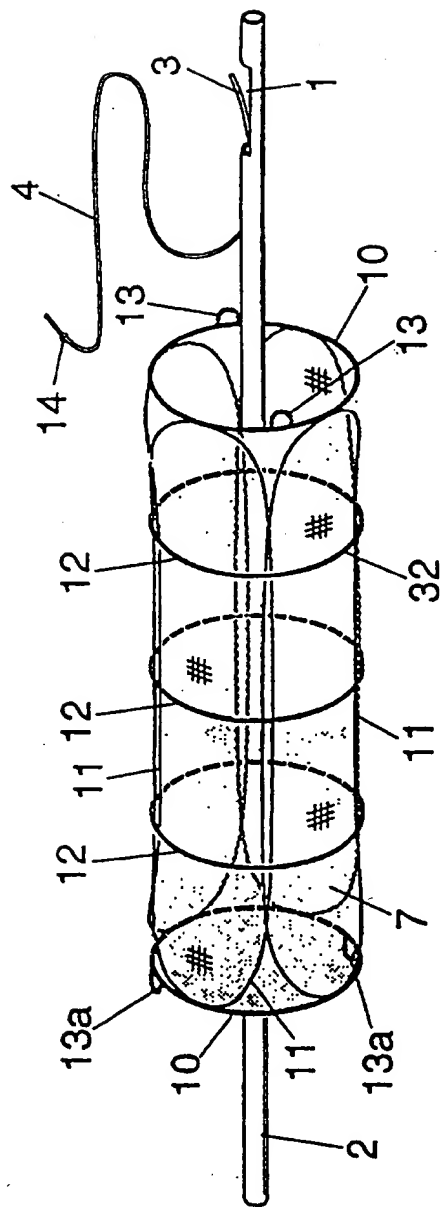


FIG.4



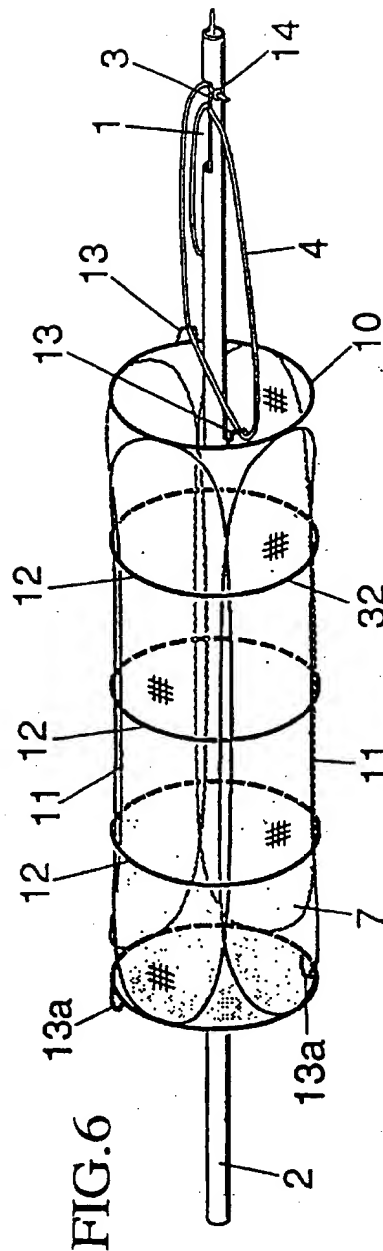
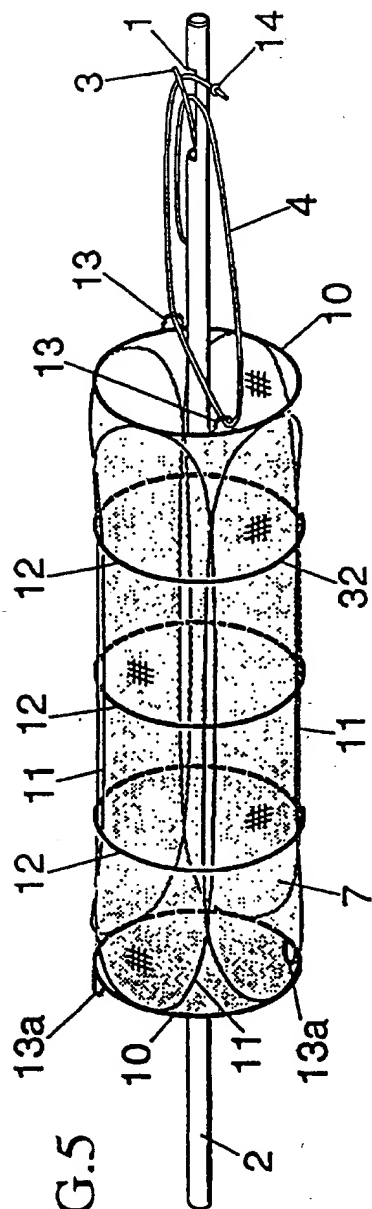


FIG.7A.

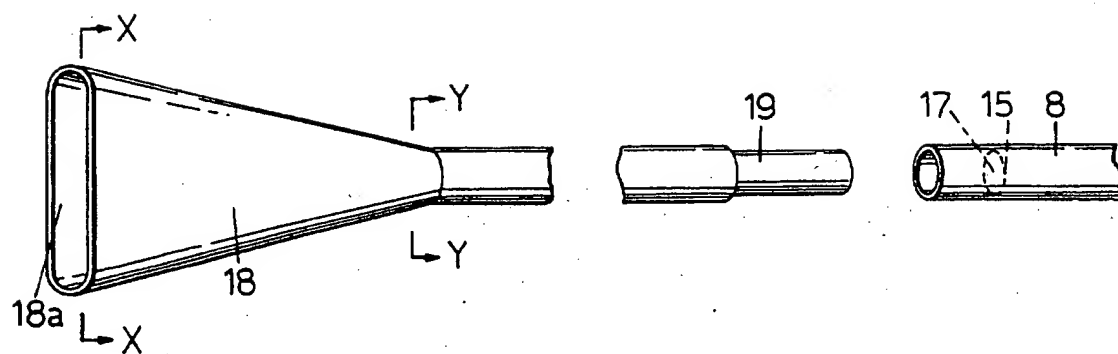


FIG.7B.

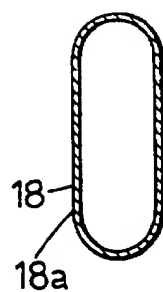


FIG.7C.

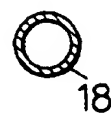


FIG.8

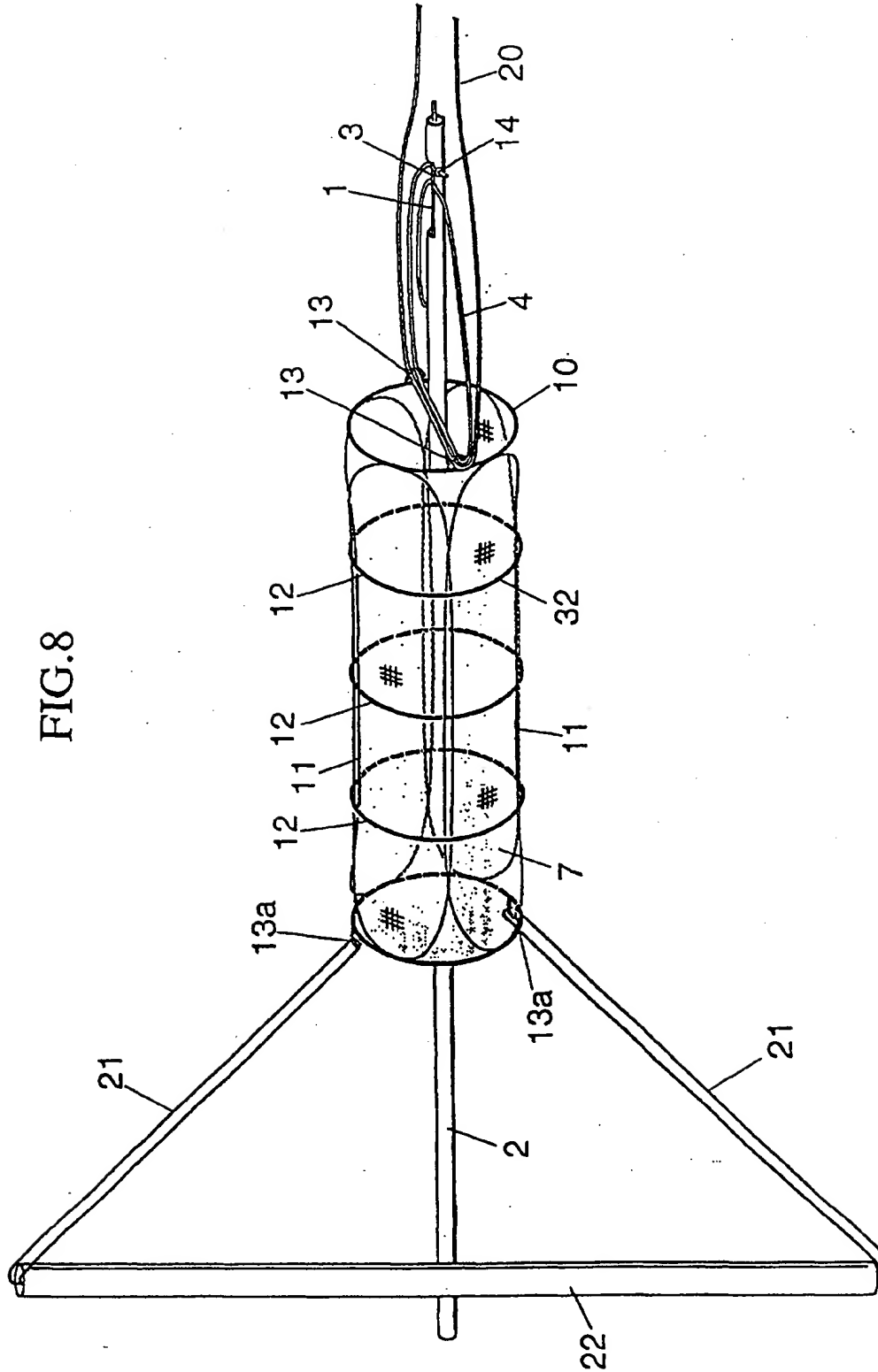
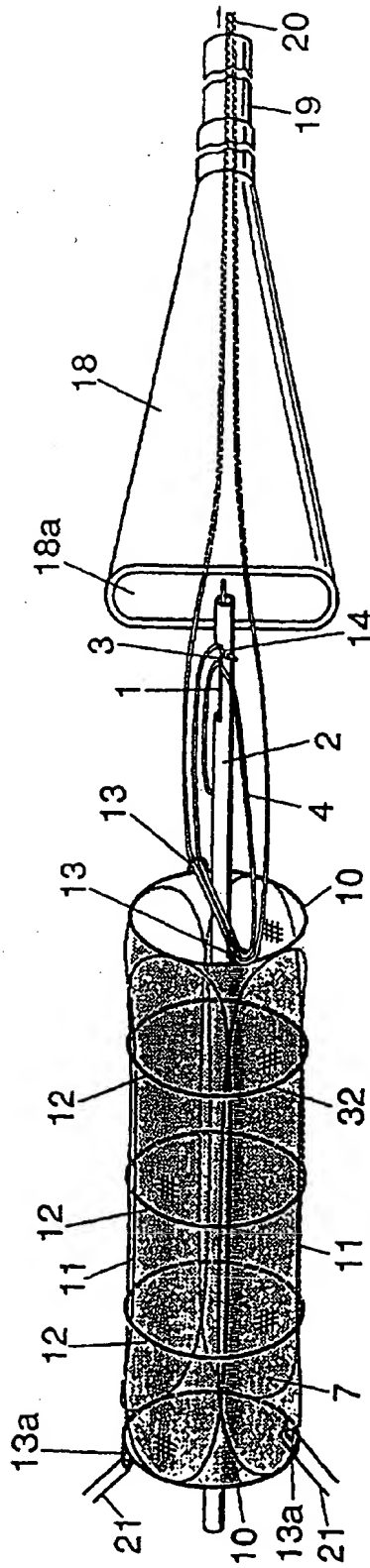


FIG.9



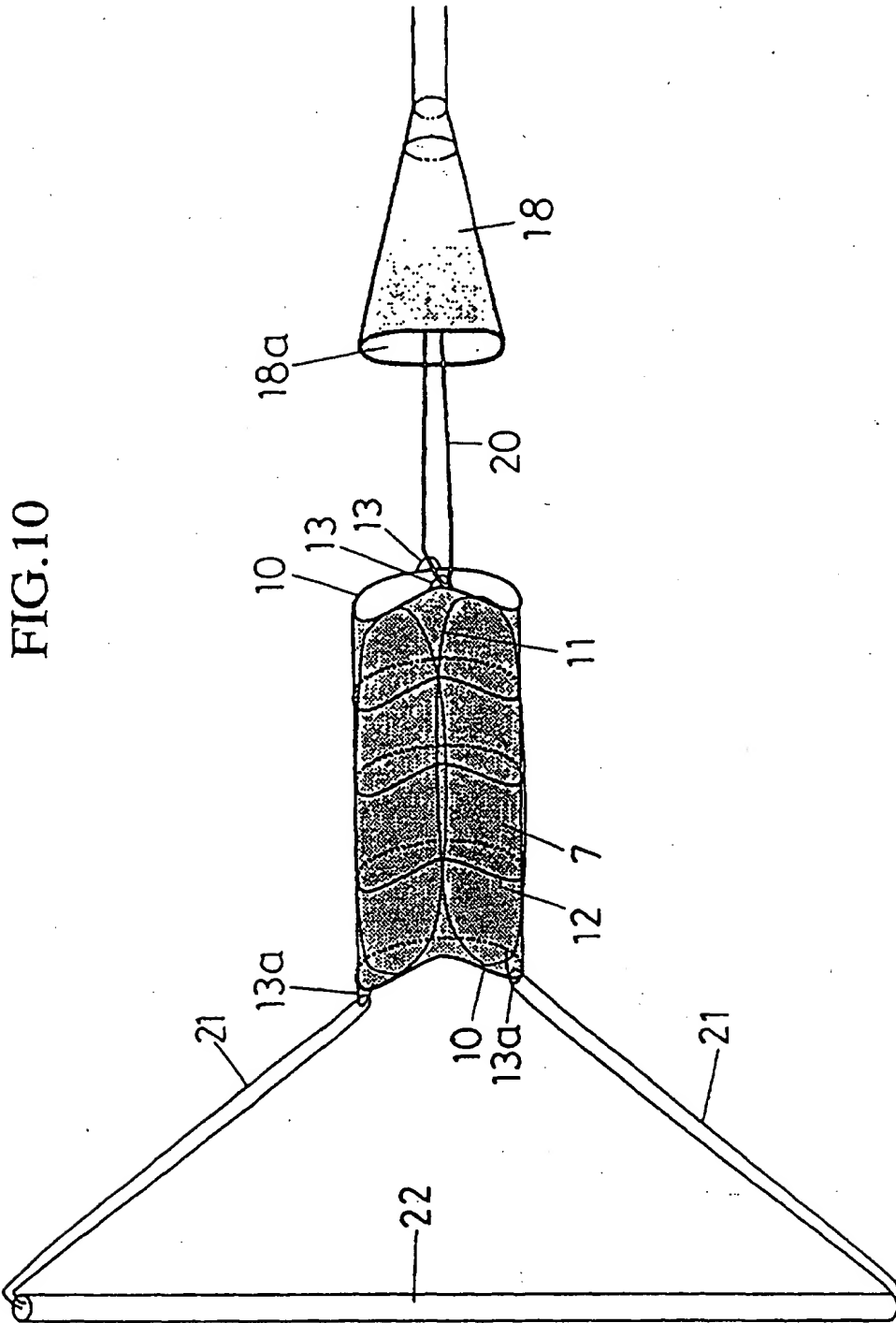


FIG.11

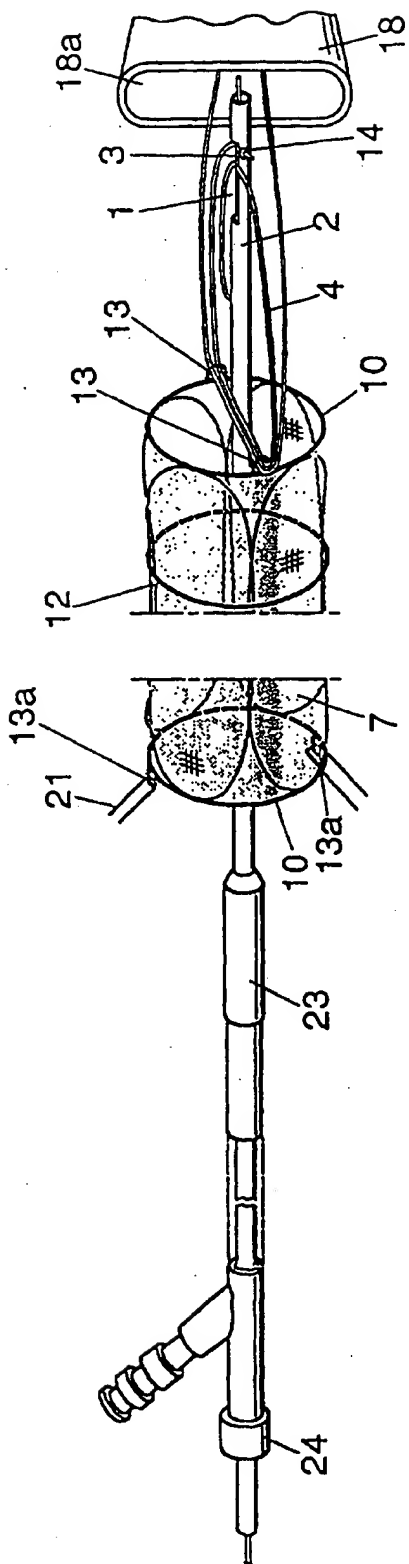


FIG.12

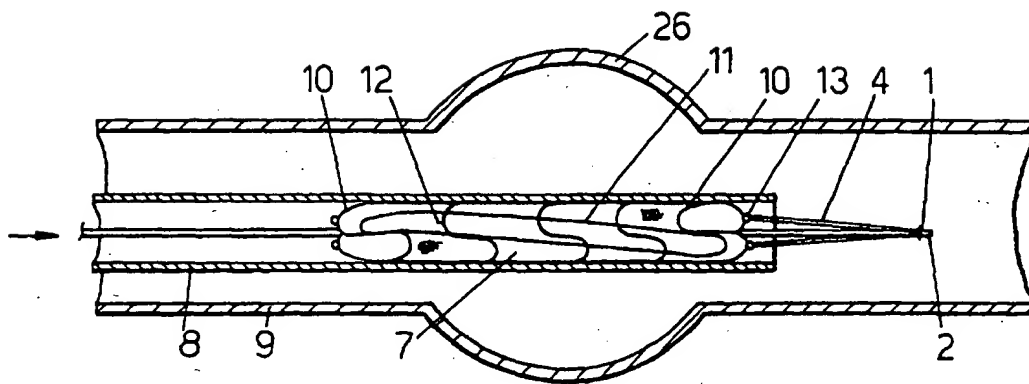


FIG.13

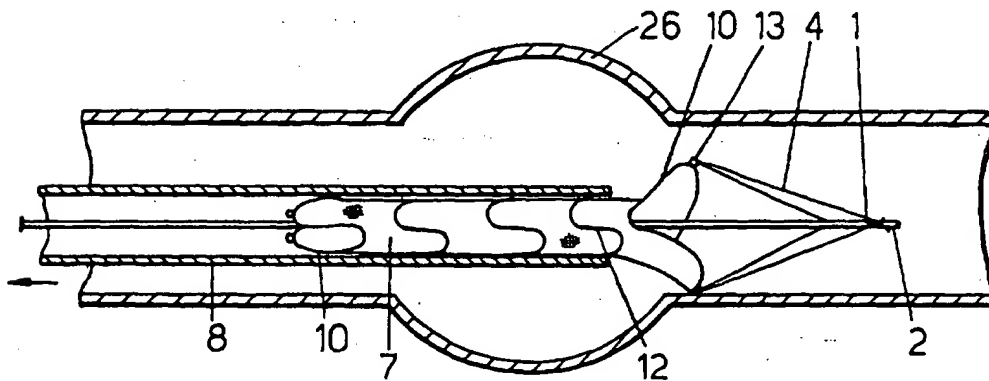


FIG.14A.

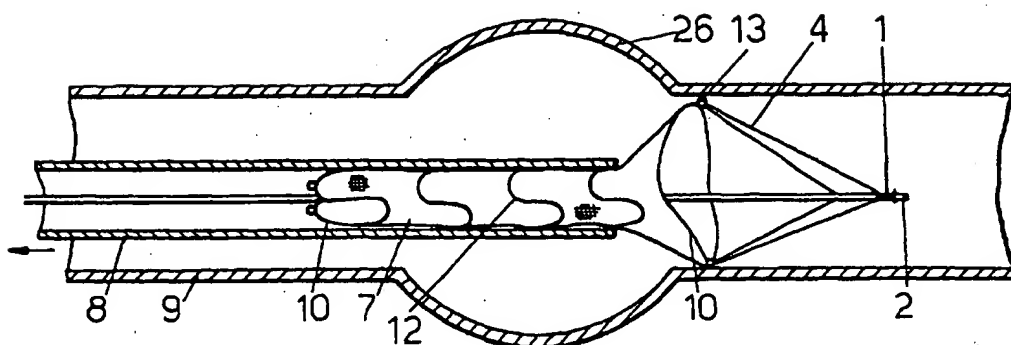


FIG.14B.

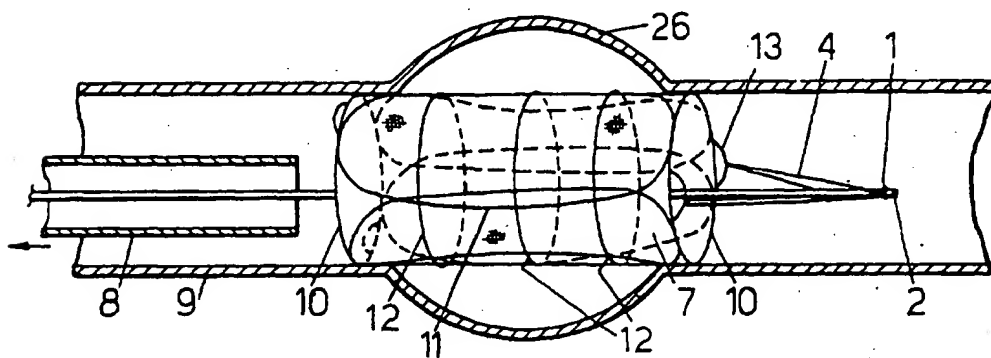


FIG.15

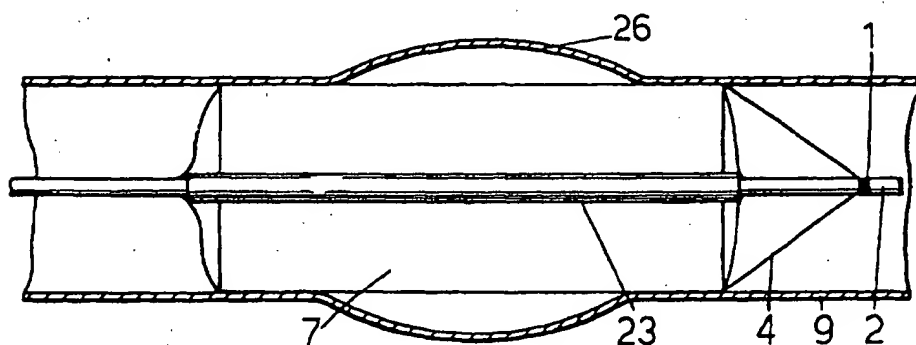


FIG.16

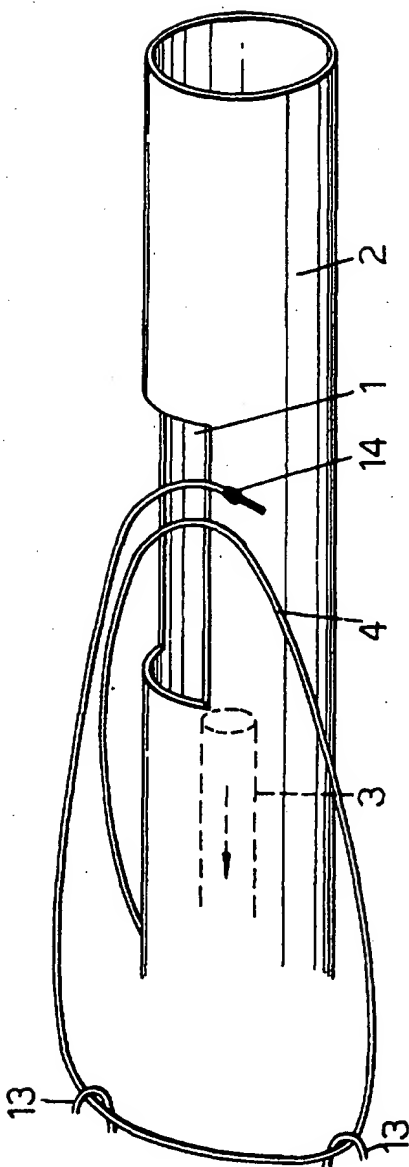


FIG.17A

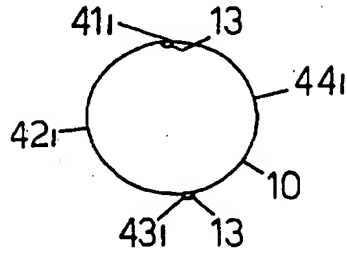


FIG.17B

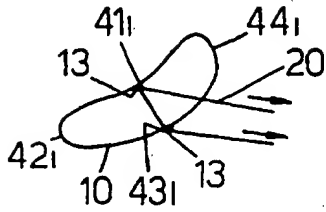


FIG.17C.

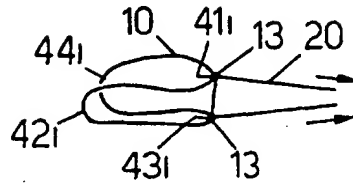


FIG.18A

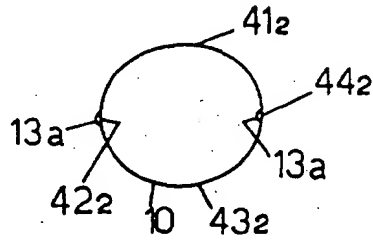


FIG.18B

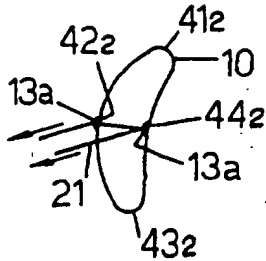


FIG.18C.

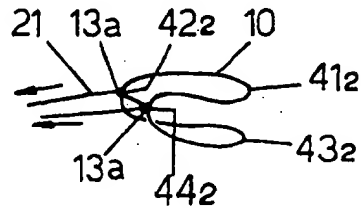


FIG.19A.

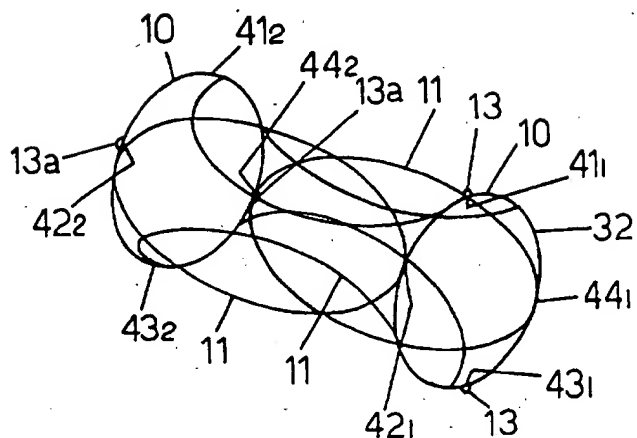


FIG.19B.

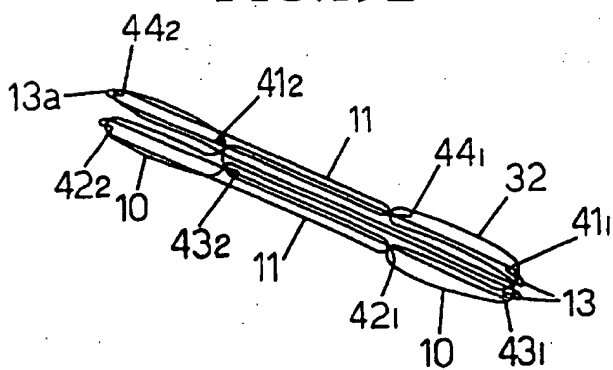


FIG.20

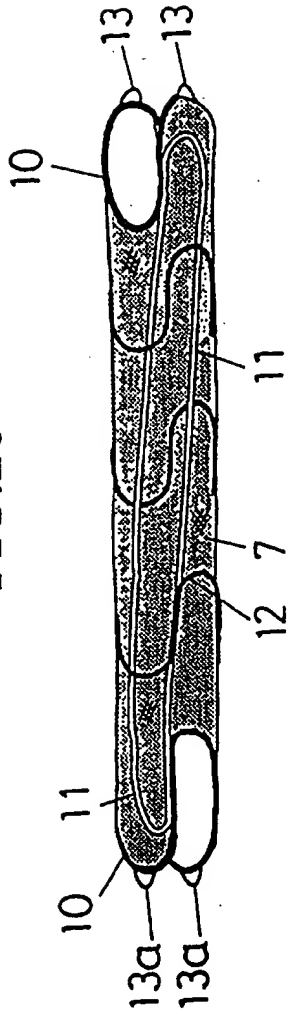


FIG.21

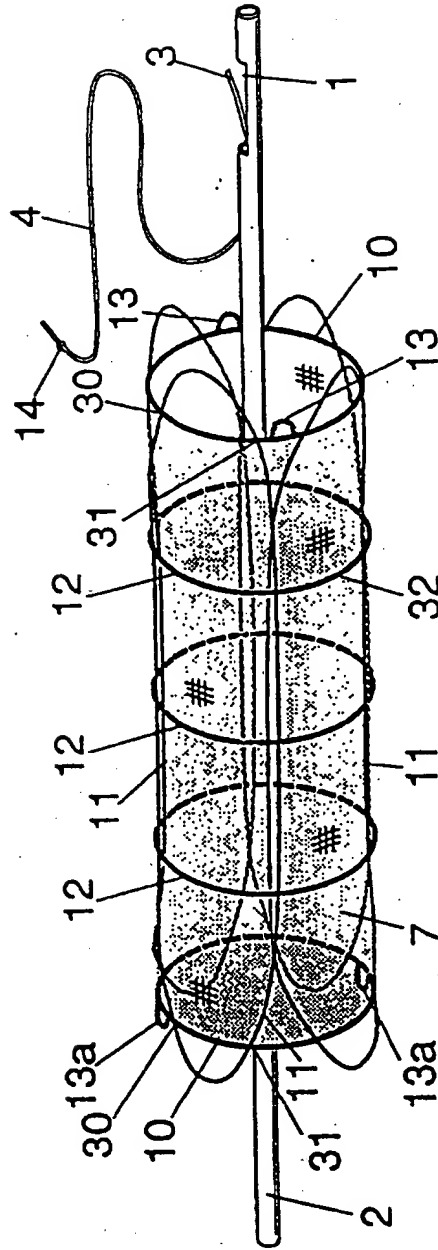


FIG.22A.

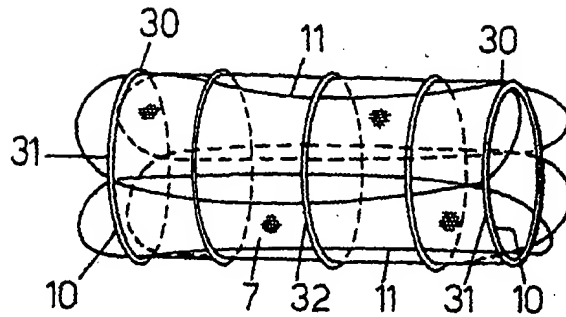


FIG.22B.

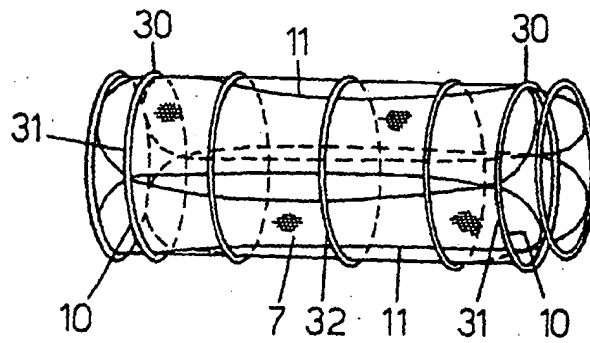


FIG.23

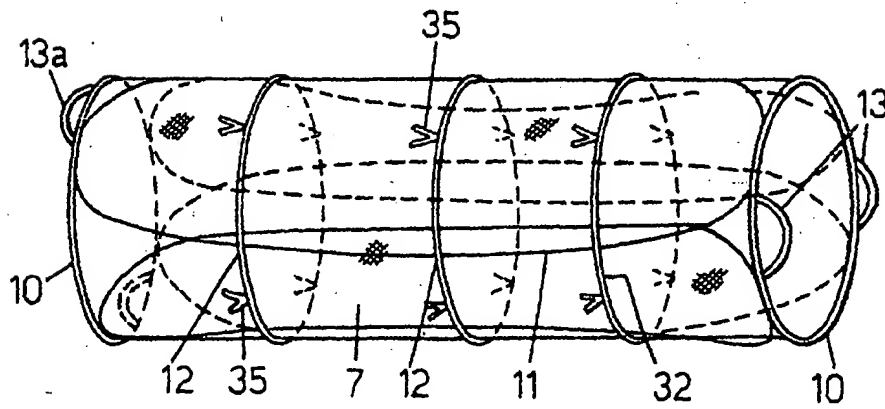


FIG.24

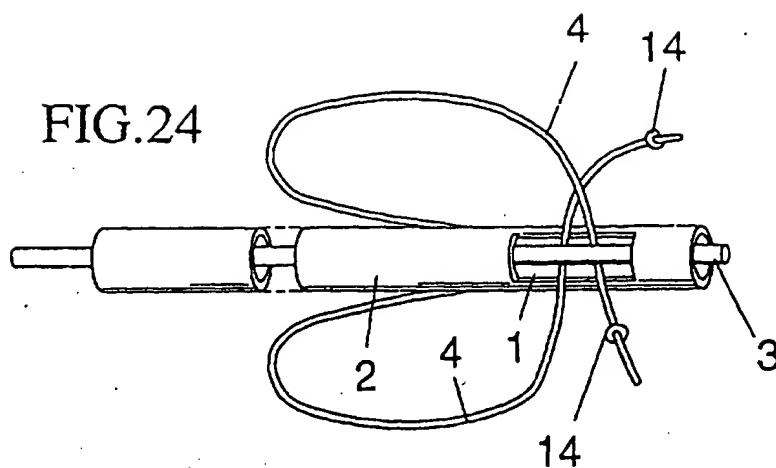


FIG.25

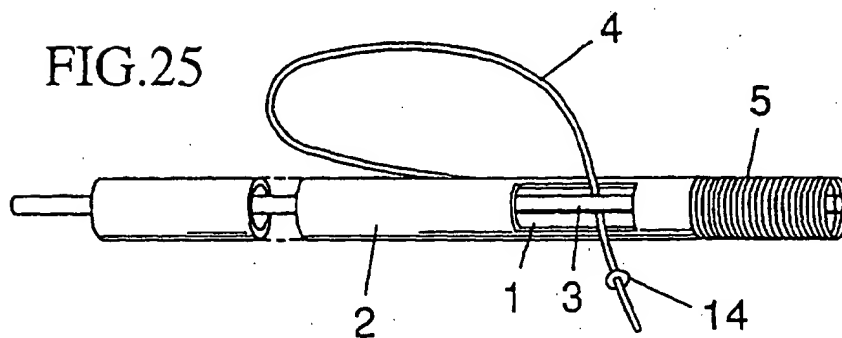


FIG.26

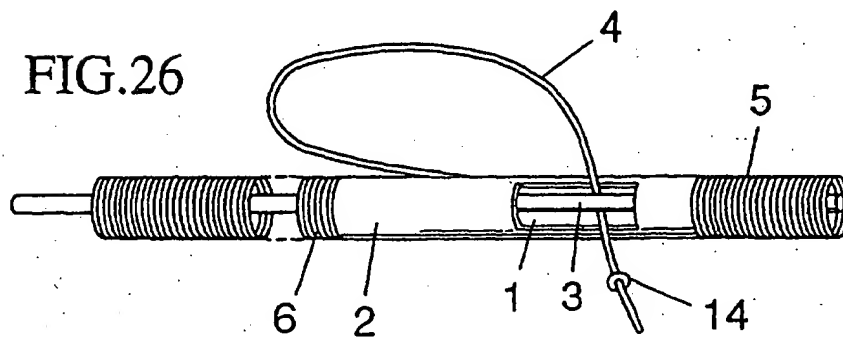


FIG. 27

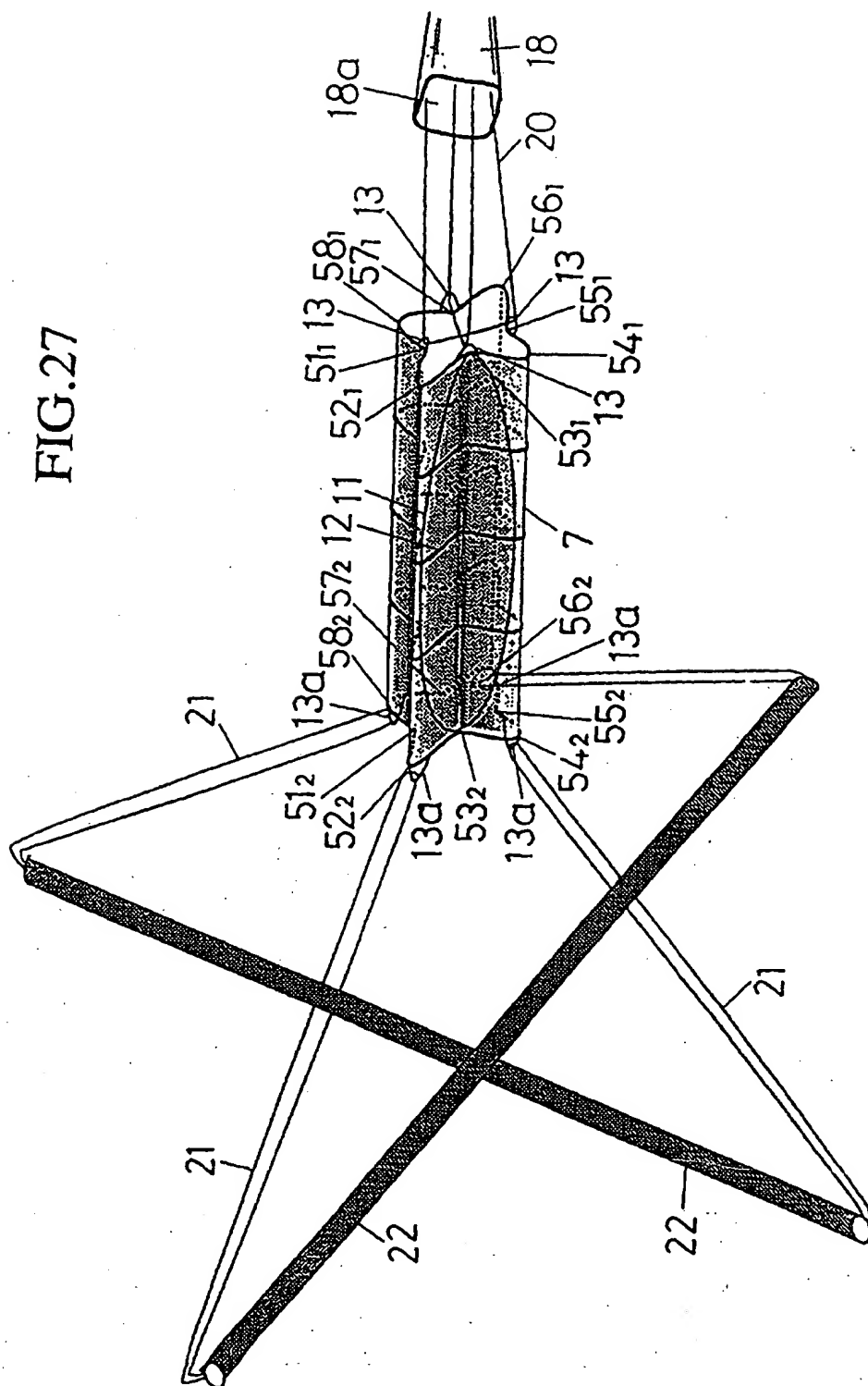


FIG.28

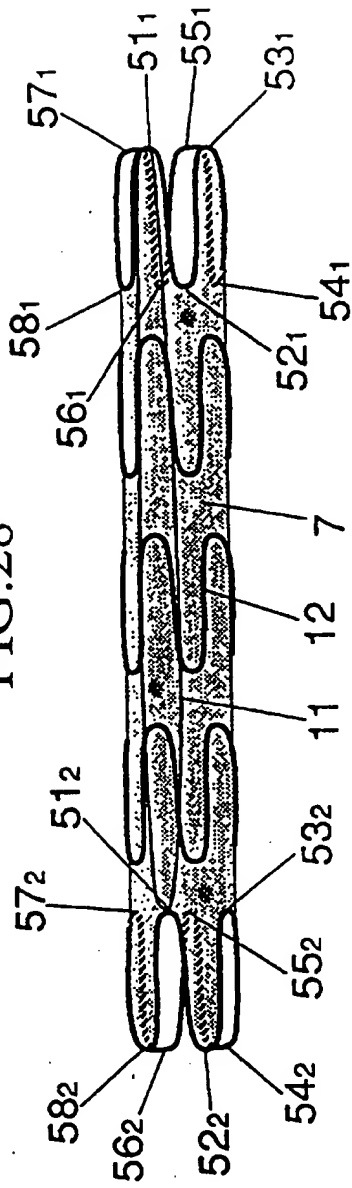


FIG.29

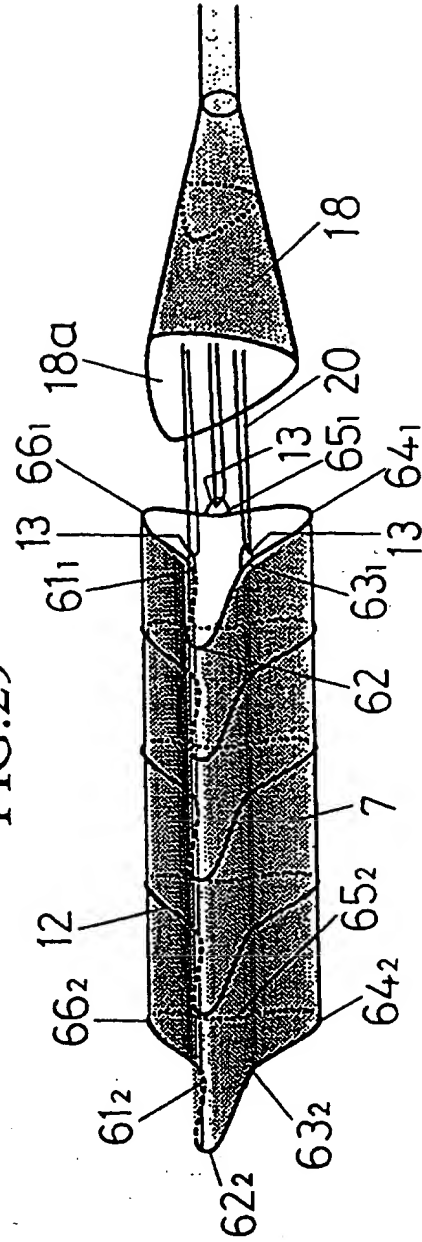


FIG.30

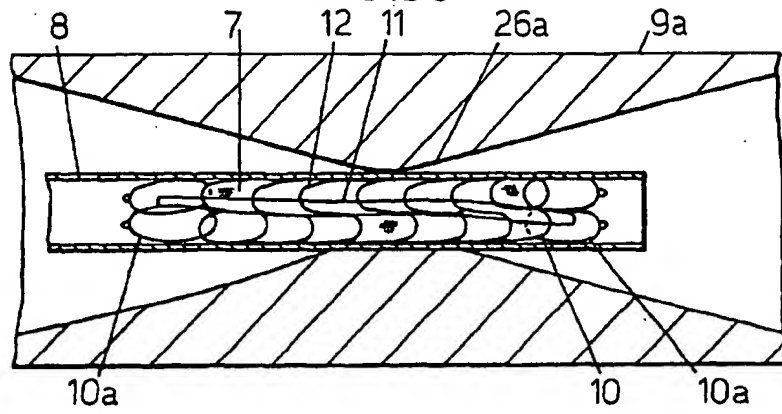


FIG.31

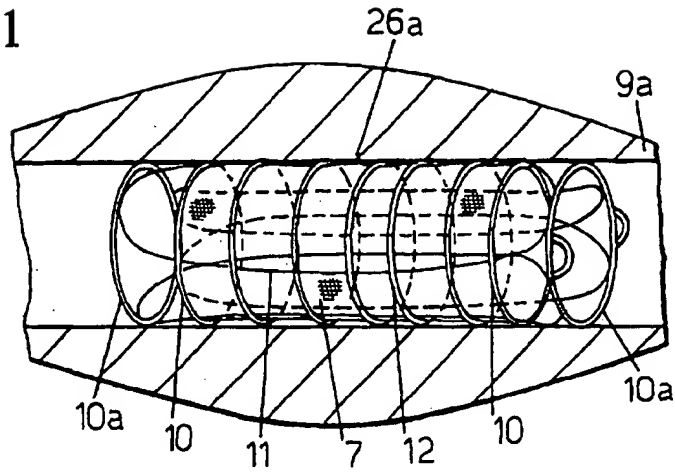


FIG.32

